

## APPENDIX I: The Claims on Appeal

1. A cryopreservation medium comprising a balanced electrolyte solution incorporating at least one cryoprotective agent that is arabinogalactan, or a biological or functional equivalent thereof, which agent is present in an amount of 1% w/v to 40% w/v, and freshly isolated lymphocytes, hematopoietic stem cells, lymphocytes which are activated or genetically modified *ex vivo*, or a combination thereof, wherein the medium does not comprise dimethylsulfoxide or serum, and wherein the arabinogalactan, biological or functional equivalent thereof, in the medium results in a high post-thaw survival rate for the freshly isolated lymphocytes, hematopoietic stem cells, or lymphocytes which are activated or genetically modified *ex vivo*.
2. The cryopreservation medium of claim 1, 53 or 54 wherein the cells are peripheral blood lymphocytes or lymphocytes which are activated or genetically modified *ex vivo*.
3. The cryopreservation medium of claim 1 that comprises arabinogalactan.
4. The cryopreservation medium of claim 1 further comprising a cryoprotective agent that penetrates the cell membrane.
5. The cryopreservation medium of claim 4 wherein the cryoprotective agent that penetrates the cell membrane is glycerol or propylene glycol.
6. The cryopreservation medium of claim 1 further comprising a cryoprotective agent other than the arabinogalactan, biological or functional equivalent thereof, which does not penetrate the cell membrane.
7. The cryopreservation medium of claim 1 which does not comprise protein.
8. The cryopreservation medium of claim 1 which is infusible.

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- ~~11.~~ The cryopreservation medium of claim 1 wherein the cells are human cells.
- ~~12.~~ The cryopreservation medium of claim 1 wherein the cells are non-human vertebrate cells.
14. A composition suitable for administration to a human, comprising a suspension of cells in a cryopreservation medium comprising a balanced electrolyte solution incorporating at least one cryoprotective agent that is arabinogalactan, or a biological or functional equivalent thereof, and a cryoprotective agent that penetrates the cell membrane, wherein the arabinogalactan, or a biological or functional equivalent thereof, is present in an amount of 1% w/v to 40% w/v, wherein the cells are freshly isolated lymphocytes, hematopoietic stem cells, lymphocytes which are activated or genetically modified *ex vivo*, or a combination thereof, wherein the medium does not comprise dimethylsulfoxide or serum, and wherein the arabinogalactan, biological or functional equivalent thereof, results in a high post-thaw survival rate for the freshly isolated lymphocytes, hematopoietic stem cells, or lymphocytes which are activated or genetically modified *ex vivo*.
- ~~16.~~ The composition of claim 14 wherein the cells are peripheral blood lymphocytes.
- ~~17.~~ The composition of claim 14 wherein at least one of the cryoprotective agents is arabinogalactan.
- ~~19.~~ The composition of claim 14 wherein the cryoprotective agent that penetrates the cell membrane is glycerol or propylene glycol.
- ~~20.~~ The composition of claim 14 further comprising a cryoprotective agent other than arabinogalactan, biological or functional equivalent thereof, which does not penetrate the cell membrane.

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21. The composition of claim 14 which does not comprise protein.
22. The composition of claim 14 which is infusible.
24. The composition of claim 14 wherein the cells are human cells.
26. A method for preserving cells comprising:
- (a) contacting cells with a cryopreservation medium comprising a balanced electrolyte solution and at least one cryoprotective agent that is arabinogalactan, or a biological or functional equivalent thereof, in an amount of 1% w/v to 40% w/v, to yield a cell suspension, wherein the cells are freshly isolated lymphocytes, hematopoietic stem cells, lymphocytes which are activated or genetically modified *ex vivo*, or a combination thereof, wherein the medium does not comprise dimethylsulfoxide or serum, and wherein the arabinogalactan, biological or functional equivalent thereof, in the medium results in a high post-thaw survival rate for the freshly isolated lymphocytes, hematopoietic stem cells, or lymphocytes which are activated or genetically modified *ex vivo*; and
  - (b) freezing the cell suspension to yield a frozen cell suspension.
27. The method of claim 26 further comprising thawing the frozen cell suspension under conditions that maintain cell viability.
28. The method of claim 26 wherein the cells are human cells.
30. The method of claim 26, 57 or 58 wherein the cells are peripheral blood lymphocytes or lymphocytes which are activated or genetically modified *ex vivo*.
31. A frozen composition comprising i) a balanced electrolyte solution, ii) at least one cryoprotective agent that is arabinogalactan, or a biological or functional equivalent thereof, in an amount of 1% w/v to 40% w/v, and iii) freshly isolated lymphocytes, hematopoietic stem cells, lymphocytes which are activated or genetically modified *ex*

*vivo*, or a combination thereof, wherein the composition does not comprise dimethylsulfoxide or serum, and wherein the arabinogalactan, biological or functional equivalent thereof, results in a high post-thaw survival rate for the freshly isolated lymphocytes, hematopoietic stem cells, or lymphocytes which are activated or genetically modified *ex vivo*.

~~32.~~ A frozen hematopoietic cell-containing composition made according to the method of claim 26.

~~33.~~ The cryopreservation medium of claim 5 wherein the cryoprotective agent that penetrates the cell membrane is glycerol.

~~34.~~ The cryopreservation medium of claim 33 wherein the concentration of glycerol is about 1% to about 3%.

37. A cryopreservation medium comprising a balanced electrolyte solution, at least one cryoprotective agent that is arabinogalactan, or a biological or functional equivalent thereof, in an amount of 1% w/v to 40% w/v and freshly isolated lymphocytes, hematopoietic stem cells, lymphocytes which are activated or genetically modified *ex vivo*, or a combination thereof, wherein the medium does not comprise dimethylsulfoxide or serum, wherein the balanced electrolyte solution is selected from the group consisting of lactated Ringer's solution, PlasmaLyte-A™, Normosol-R™, Veen-D™, Polysal®, and Hank's balanced salt solution, and wherein the arabinogalactan, biological or functional equivalent thereof, results in a high post-thaw survival rate for the freshly isolated lymphocytes, hematopoietic stem cells, or lymphocytes which are activated or genetically modified *ex vivo*.

~~38.~~ The cryopreservation medium of claim 37 wherein the lymphocytes are peripheral blood lymphocytes.

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- ~~39.~~ The cryopreservation medium of claim 37 wherein the agent is arabinogalactan.
  - ~~40.~~ The cryopreservation medium of claim 37 further comprising a cryoprotective agent that penetrates the cell membrane.
  - ~~41.~~ The cryopreservation medium of claim 40 wherein the cryoprotective agent that penetrates the cell membrane is glycerol or propylene glycol.
  - ~~42.~~ The cryopreservation medium of claim 37 further comprising a cryoprotective agent other than arabinogalactan or a biological or functional equivalent thereof which does not penetrate the cell membrane.
  - ~~43.~~ The cryopreservation medium of claim 37 which does not comprise protein.
  - ~~44.~~ The cryopreservation medium of claim 37 which is infusible.
  - ~~47.~~ The cryopreservation medium of claim 37 wherein the cells are human cells.
  - ~~48.~~ The cryopreservation medium of claim 37 wherein the cells are non-human vertebrate cells.
  - ~~49.~~ The method of claim 26 wherein the medium comprises arabinogalactan.
  - ~~50.~~ The method of claim 26 further comprising a cryoprotective agent that penetrates the cell membrane.
  - ~~51.~~ The method of claim 50 wherein the cryoprotective agent that penetrates the cell membrane is glycerol or propylene glycol.

52. The method of claim 26 wherein the lymphocytes which are modified *ex vivo* are activated lymphocytes or genetically modified lymphocytes.
53. A cryopreservation medium comprising a balanced electrolyte solution incorporating at least one cryoprotective agent that is arabinogalactan, which is present in an amount of 1% w/v to 40% w/v, and freshly isolated lymphocytes, hematopoietic stem cells, lymphocytes which are activated or genetically modified *ex vivo*, or a combination thereof, wherein the medium does not comprise dimethylsulfoxide or serum, and wherein the arabinogalactan in the medium results in a high post-thaw survival rate for the freshly isolated lymphocytes, hematopoietic stem cells, or lymphocytes which are activated or genetically modified *ex vivo*.
54. A cryopreservation medium comprising a balanced electrolyte solution incorporating arabinogalactan, which is present in an amount of 1% w/v to 40% w/v, glycerol in amount of 0.5% to about 20%, and freshly isolated lymphocytes, hematopoietic stem cells, lymphocytes which are activated or genetically modified *ex vivo*, or a combination thereof, wherein the medium does not comprise dimethylsulfoxide or serum, and wherein the arabinogalactan and glycerol in the medium result in a high post-thaw survival rate for the freshly-isolated lymphocytes, hematopoietic stem cells, or lymphocytes which are activated or genetically modified *ex vivo*.
55. A frozen composition comprising i) a balanced electrolyte solution, ii) at least one cryoprotective agent that is arabinogalactan in an amount of 1% w/v to 40% w/v, and iii) freshly isolated lymphocytes, hematopoietic stem cells, lymphocytes which are activated or genetically modified *ex vivo*, or a combination thereof, wherein the composition does not comprise dimethylsulfoxide or serum, and wherein the arabinogalactan in the composition results in a high post-thaw survival rate for the freshly isolated lymphocytes, hematopoietic stem cells, or lymphocytes which are activated or genetically modified *ex vivo*.

56. A frozen composition comprising i) a balanced electrolyte solution, ii) at least one cryoprotective agent that is arabinogalactan in an amount of 1% w/v to 40% w/v, iii) glycérol in amount of 0.5% to about 20%, and iv) freshly isolated lymphocytes, hematopoietic stem cells, lymphocytes which are activated or genetically modified *ex vivo*, or a combination thereof, wherein the composition does not comprise dimethylsulfoxide or serum, and wherein the arabinogalactan and glycerol in the composition result in a high post-thaw survival rate for the freshly isolated lymphocytes, hematopoietic stem cells, or lymphocytes which are activated or genetically modified *ex vivo*.

57. A method for preserving cells comprising: freezing a cell suspension comprising cells and a cryopreservation medium comprising a balanced electrolyte solution, arabinogalactan in an amount of 1% w/v to 40% w/v, and glycerol in amount of 0.5% to about 20%, to yield a cell suspension, wherein the cells are freshly isolated lymphocytes, hematopoietic stem cells, lymphocytes which are activated or genetically modified *ex vivo*, or a combination thereof, wherein the medium does not comprise dimethylsulfoxide or serum, and wherein the arabinogalactan and glycerol in the medium result in a high post-thaw survival rate for the freshly isolated lymphocytes, hematopoietic stem cells, or lymphocytes which are activated or genetically modified *ex vivo*.

58. A method for preserving cells comprising:  
(a) contacting cells with a cryopreservation medium comprising a balanced electrolyte solution and at least one cryoprotective agent that is arabinogalactan, in an amount of 1% w/v to 40% w/v, to yield a cell suspension, wherein the cells are freshly isolated lymphocytes, hematopoietic stem cells, lymphocytes which are activated or genetically modified *ex vivo*, or a combination thereof, wherein the medium does not comprise dimethylsulfoxide or serum, and wherein the arabinogalactan in the composition results in a high post-thaw survival rate for the freshly isolated lymphocytes, hematopoietic stem cells, or lymphocytes which are activated or genetically modified *ex vivo*; and

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(b) freezing the cell suspension at a cooling rate of about 1° to about 10° C/minute to yield a frozen cell suspension.

59. The medium of claim 1, 37, 53 or 54 wherein the post-thaw survival rate is at least 40%.

60. The method of claim 26, 57 or 58 wherein the post-thaw survival rate is at least 40%.



**APPENDIX II: Office Actions, Amendments, Responses and Rule 132 Declarations**

1. Office Action dated October 25, 2000
2. Amendment dated February 26, 2001
3. Final Office Action dated April 16, 2001
4. Amendment dated August 27, 2001 and Rule 132 Declaration of Dr. Allison Hubel
5. Advisory Action dated September 7, 2001
6. Request for Continued Examination dated October 16, 2001
7. Office Action dated February 22, 2002
8. Amendment dated May 2, 2002
9. Final Office Action dated May 30, 2002
10. Response dated October 30, 2002 and Rule 132 Declaration of Dr. John Bischof
11. Advisory Action dated November 18, 2002
12. Request for Continued Examination dated November 27, 2002
13. Office Action dated December 23, 2002